COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.3.2009
C(2009)2293

NOT FOR PUBLICATION

COMMISSION DECISION

of 25.3.2009

on the renewal of the marketing authorisation for the medicinal product for human use "Lysodren - Mitotane", granted by Decision C(2004)1765

(ONLY THE FRENCH TEXT IS AUTHENTIC)

COMMISSION DECISION

of 25.3.2009

on the renewal of the marketing authorisation for the medicinal product for human use "Lysodren - Mitotane", granted by Decision C(2004)1765

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Laboratoire HRA Pharma, on 15 September 2008, under Article 14(2) of Regulation (EC) No 726/2004 with a view to the renewal of the marketing authorisation for the medicinal product "Lysodren - Mitotane"

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 22 January 2009,

Whereas:

(1) On the basis of a re-evaluation by the Agency of the risk-benefit balance following the consideration of a consolidated file, it appears that the medicinal product "Lysodren - Mitotane", entered in the Community register of medicinal products under number(s) EU/1/04/273/001 and authorised by Commission Decision C(2004)1765 of 28 April 2004, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2].

(2) The marketing authorisation which expires on 30 April 2009 should therefore be renewed.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 311, 28.11.2001, p. 67.

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2004)1765 of 28 April 2004 which expires on 30 April 2009 is renewed.

Article 2

Decision C(2004)1765 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

This Decision is addressed to Laboratoire HRA Pharma, 15, rue Béranger, 75003 Paris, France.

Done at Brussels, 25.3.2009

For the Commission
Heinz ZOUREK
Director-General